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L1: Entry 29 of 53

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Jun 14, 2005

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TITLE: Micelles

Detailed Description Text (57):

When using a lyophilized drug product, clinicians typically reconstitute the freeze-dried preparation in physiologically acceptable solutions. It is desirable to be able to store the reconstituted solution either at room temperature or under refrigeration. Freeze-dried preparations of the micelles described herein are rehydratable with water or an aqueous dextrose solution suitable for intravenous administration, with the micelle hydrodynamic diameter distribution remaining unchanged. Such reconstituted micelle solutions can be stored at room temperature or refrigerated temperatures with no change in the micelle hydrodynamic diameter.

Detailed Description Text (65):

Micelles of E5564 having a hydrodynamic diameter of 7 nm to 9 nm (Table 1) prepared as described above were lyophilized. After lyophilization the micelles were reconstituted with water diluted in an aqueous dextrose solution (Table 2). The micelle hydrodynamic diameter of E5564 in the reconstituted solutions remained at 7 nm to 9 nm in the reconstituted physiologically acceptable solutions under various conditions. The E5564 micelle hydrodynamic diameter was stable when reconstituted in water for 24 hours at 25.degree. C. 5564 micelle hydrodynamic diameter was unchanged after dextrose solution maintained at pH 7.4 and storage for 24 hours at 25.degree. C. or 72 hours at 2 to 8.degree. C. (Table 2). The E5564 micelle hydrodynamic diameter was stable as a drug protect stored in a lyophilized state at 25.degree. C. under 60% relative humidity, or under refrigeration (Table 3). Further, the E5564 micelle hydrodynamic diameter, in micelles prepared according to the methods of the present invention, was stable under stimulated administration conditions using representative infusion equipment (Table 4).

[Previous Doc](#)[Next Doc](#)[Go to Doc#](#)